

MDL No. 02419  
Docket No. 1:13-md-2419-RWZ

Farthing v. Box Hill Surgery Center, LLC, et al.  
No. 1:14-cv-14036-RWZ

EXHIBIT  
3

### **GENERAL RESPONSES**

1. The information supplied in these responses is not based solely on the knowledge of the Defendants to whom the Request is addressed, but includes the knowledge of the Defendants' agents, representatives and attorneys, unless privileged.
2. The word usage and sentence structure may be that of the Defendants' agents, representatives, and/or attorneys assisting in the preparation of these responses and, thus, does not necessarily purport to be the precise language of the responding parties.
3. The Request has been interpreted and responded to in accordance with the Federal Rules of Civil Procedure, plain English usage and, to the extent not specifically challenged by objection, the definitions and instructions included with the Request.

### **GENERAL OBJECTIONS**

- A. The Defendants object to these requests on the grounds that they exceed and/or are in contravention of the Federal Rules of Civil Procedure and the Discovery Guidelines of the United States District Court.
- B. The Defendants object to each and every request to the extent the request is overly broad, unduly burdensome, harassing, repetitious, vague and/or ambiguous, and to the extent that the Request purports to require the disclosure of information beyond the scope of admissible evidence under the Federal Rules.
- C. The Defendants object to each and every request to the extent that Plaintiffs seek information subject to the attorney-client and/or work product privileges or other applicable privileges, including the opinions, mental impressions, conclusions or legal theories of its attorneys, accountants or other representatives. Inadvertent production or exposure of any such document shall not constitute a waiver of such privilege or immunity or of any other ground of objection to the admissibility of such documents or of any information contained therein.
- D. The Defendants do not waive any protections or privileges by responding to these requests. Inadvertent production or exposure of any such document shall not constitute a waiver of such privilege or immunity or of any other ground of objection to the admissibility of such documents or of any information contained therein.
- E. The Defendants object to each and every request to the extent the request seeks information that is not relevant to these cases, or information that is not likely to lead to the discovery of admissible evidence in these cases.

F. The Defendants object to all requests and to the definitions and instructions set forth therein, to the extent they impose duties which exceed or alter the duties imposed by the Federal Rules.

G. The Defendants' objections and responses to the Requests are based on information now available to them, and are made without prejudice to the Defendants' right to assert additional objections should they discover additional grounds for objection. That the Defendants have responded to any request is not intended and shall not be construed as a waiver by them of any objection to any request.

H. The Defendants have not yet completed discovery in this lawsuit and, therefore, reserve the right to file supplemental responses if, and when, such additional information comes into their possession.

I. By providing the information requested, the Defendants do not waive any objections to their admission into evidence on the grounds of relevance, materiality, or any other proper grounds for objection.

J. The Defendants object to all Requests to the extent that they seek information regarding trade secrets or other confidential, commercial, proprietary, technical, financial, business plans and/or other material which would allow Plaintiffs and/or third persons to obtain competitive information.

K. The Defendants object to all requests to the extent that they seek "all" communications and "all" documents on the ground that they cannot know all communications or documents which may exist.

L. No incidental or implied admissions are intended by a response provided by the Defendants to any request. That the Defendants have responded to any request is not an admission that they accept or admit the existence of any facts set forth or assumed by such request or that the making of such a response constitutes admissible evidence.

M. Neither the Defendants' agreement to produce nor their objection to the production of any information or documents or any category of information or documents is to be construed as an admission or acknowledgement that any information or documents exist within such category or categories.

N. The Defendants object to any request to the extent that it requires disclosure of information banned and/or protected from disclosure by law.

O. The Defendants make these responses subject to the reservation of their rights to object to the introduction into evidence in this or any other action of any information or material contained herein or produced hereunder upon any ground, including, but not limited to, relevancy, materiality, competency, and hearsay.

P. The Defendants object to those requests in which the Plaintiffs have provided their interpretation of the meaning of a document or purport to summarize the contents of a document in variance of the actual terms contained within such a document in that the Plaintiffs'

allegations are conclusions of law and/or contain characterizations for which no further response is required beyond reference to the actual document cited.

Q. The Defendants generally object to the characterizations throughout the Request. The Defendants' responses do not constitute their agreement with the characterizations contained in the Request.

R. The Defendants object to the requests to the extent they seek documents or information already in the custody or control of the Plaintiffs or seek documents or information, which may be obtained by Plaintiffs more conveniently, less expensively, and with less burden than by the Defendants or by these requests.

S. The Defendants object to each request that seeks the disclosure of documents that are available to the public.

T. These objections are hereby incorporated into each specific objection and response. Citation to a particular general response and any specific objection below is not a waiver of any of the general objections not cited therein.

U. All responses stated below incorporate the above-stated objections and are provided subject to and without waiving any of the objections stated above. The fact that the Defendants choose not to repeat each of the foregoing objections for each specific request shall not constitute a waiver of any of the foregoing objections.

### RESPONSES

1. *MPA and Triamcinolone*: Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and Triamcinolone from New England Compounding Pharmacy, Inc. ("NECP") that the CDC has identified as contaminated including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identify of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied) or any other compounded steroid medication encompassed by this request.

Response No. 1: Defendants object to this Request. The request is vague, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, Defendants did not purchase Triamcinolone from New England Compounding Pharmacy, Inc. ("NECP" or "NECC") and have no documents responsive to that part of the Request. As the Request relates to

methylprednisolone acetate ("MPA"), documents responsive to this Request are attached. Names, identification numbers, and phone numbers have been redacted of patients who are not parties to any lawsuits filed in these matters against the Defendants, or who have not been identified as represented by counsel as potential plaintiffs. (See Docket No. 572 at 19-20.) In addition, Defendants' credit card information was also redacted as the specific card number is not relevant and risks identity theft. It should also be noted that the packing slips do not say "New England Compounding Pharmacy, Inc." or "NECP," but rather "New England Compounding Center, Inc." and "NECC." It is our understanding that those entities are one and the same. The attached and other documents are also likely available from NECC. Defendants reserve the right to supplement this response as discovery proceeds.

2. *Equivalents to MPA:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, or any other NECC compounded medication identified as contaminated by CDC, from any producer, compounding facility or manufacturer other than NECP, since 1/1/2012, including without limitations of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparations being purchased.

Response No. 2: Pursuant to this Court's Order On Motion to Quash and Objections to Subpoena, dated November 13, 2013, Defendants need not comply with this request. (Docket No. 572 at 1-2.) Without waiving said objection, Defendants have no documents responsive to this request.

3. *Cardioplegic solution:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP that the CDC has identified as contaminated including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescript order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

Response No. 3: Defendants object to this request. The request seeks documents that are not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objection, Defendants have no documents responsive to this request.

4. *Betamethasone*: Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of Betamethasone from NECP that the CDC has identified as contaminated, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for ophthalmic solution (before and after any discounts applied).

Response No. 4: Defendants object to this request. The request seeks documents that are not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objection, Defendants have no documents responsive to this request.

5. [Request No. 5 was omitted in the Revised Subpoena by Plaintiffs]

6. [Request No. 6 was omitted in the Revised Subpoena by Plaintiffs]

7. *Communications with NECP*: Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between NAME OF TARGET HEALTHCARE PROVIDER ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

Response No. 7: Defendants object to this request. The request is vague, overly broad, and unduly burdensome. Without waiving said objections, any documents responsive to this request were previously produced, but are also attached here. There may be other documents responsive to this request depending on Plaintiffs' definition of "communication," but they are duplicative of documents already attached in response to other requests.

8. *Information about NECP's qualifications*: Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company



overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

Response No. 8: Defendants object to this request. The request is vague, overly broad, and unduly burdensome, and seeks documents that are not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objection, Defendants currently have no documents responsive to this request.

9. *Communications received about fitness of NECP's products:* Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, for the medical products determined by the CDC to be contaminated, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

Response No. 9: Defendants object to this request. The request is vague, overly broad, and unduly burdensome, and seeks documents that are not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, Defendants have no documents responsive to this request other than what is produced in response to Requests No. 7 and 10.

10. *Information received from governmental entities:* Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/or agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

Response No. 10: Defendants object to this request. The request is vague, overly broad, and unduly burdensome. Without waiving said objections, please see attached. Among other things, electronic communications are produced. To the extent that those electronic communications included information protected by the attorney-client privilege, it was redacted. There was no substantive information redacted.

11. [Request No. 11 was omitted in the Revised Subpoena by Plaintiffs]

12. *Marketing information:* Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

Response No. 12: Defendants object to this request. The request is vague, overly broad, and unduly burdensome. Without waiving said objections, Defendants have attached responsive documents.

13. *Contracts with NECP:* Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

Response No. 13: Defendants object to this request. The request is vague, overly broad, and unduly burdensome. Without waiving said objections, Defendants have no documents responsive to this request.

14. *Recall notices received:* Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

Response No. 14: Defendants object to this request. The request is vague, overly broad, and unduly burdensome. Without waiving said objections, please see attached.

15. *Communications responding to recall notices:* any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communications.

Response No. 15: Defendants object to this request. The request is vague, overly broad, and unduly burdensome, and seeks documents that are not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, please see attached, as well as documents produced in response to Requests No. 7, 10 and 14. Names, identification numbers, and phone numbers have been redacted of patients who are not parties to



any lawsuits filed in these matters against the Defendants, or who have not been identified as represented by counsel as potential plaintiffs. (See Docket No. 572 at 19-20.)

16. *Compliance with USP:* Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled “Pharmaceutical Compounding – Sterile Preparations”).

Response No. 16: Defendants object to this request. The request is vague, overly broad, unduly burdensome, and seeks information that is not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, Defendants currently have no documents responsive to this request.

17. *Insurance policies:* Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal offices and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods covering any use of NECP medical products identified as contaminated by the CDC.

Response No. 17: Defendants object to this request. The request is vague, overly broad, unduly burdensome, and seeks information that is not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, responsive documents related to professional malpractice insurance were previously produced.

18. *Articles of incorporation:* Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

Response No. 18: Defendants object to this request. The request is vague, overly broad, unduly burdensome, and seeks information that is not reasonably calculated to lead to the discovery of relevant or admissible evidence. Without waiving said objections, please see attached.

Respectfully submitted,

/s/ Gregory K. Kirby  
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Ritu T. Bhambhani, M.D., and Ritu T.  
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**LOCAL RULE 7.1 CERTIFICATION**

I hereby certify that I have conferred with Plaintiffs' counsel and attempted in good faith to resolve or narrow the issues.

/s/ Gregory K. Kirby  
Gregory K. Kirby

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 9<sup>th</sup> day of March, 2015, a copy of the foregoing Response to Revised Subpoena on behalf of Defendants Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, and the referenced and attached documents, were served, via electronic and first-class mail, postage prepaid, upon:

Kimberly A. Dougherty  
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Attorney and Member of the Plaintiffs' Steering Committee

/s/ Gregory K. Kirby  
Gregory K. Kirby

1

ARTICLES OF ORGANIZATION

The undersigned, with the intention of creating a Maryland Limited Liability Company files the following Articles of Organization:

(1) The name of the Limited Liability Company is: RITU BHAMBHANI, LLC

[The rest of this document is redacted  
for purposes of this filing since the rest  
is sensitive and irrelevant to the filing]